

REMARKS

By this Amendment, Applicant cancels claims 17 and 30-42, without prejudice or disclaimer. Applicant reserves the right to present the subject matter of claims 17 and 30-42 at a later date, for example, in a continuation application of this application. Applicant also amends claims 15, 18, 21, 24, 26, and 29. No new matter has been added. Thus, claims 15, 16, and 18-29 are currently pending, with claim 15 being the sole independent claim.

At page 2 of the Office Action, the Examiner asserted that Applicant's request to correct the inventorship of this nonprovisional application was deficient because certain requirements under 37 C.F.R. §1.48(a) were not fulfilled. However, Applicant respectfully notes that the petition submitted by Applicant was a Petition Under 37 C.F.R. §1.48(b) and not 37 C.F.R. §1.48(a). Accordingly, the alleged deficiencies set forth by the Examiner with regard to a Petition Under 37 C.F.R. §1.48(a) do not apply to a Petition Under 37 C.F.R. §1.48(b). That is, the requested amendment to the inventorship resulted from amendment and/or cancellation of claims so that fewer than all of the currently named inventors are actual inventors of the presently claimed subject matter. Further, Applicant asserts that the Petition Under 37 C.F.R. §1.48(b) filed on March 4, 2003 meets all the requirements of 37 C.F.R. §1.48(b). Applicant therefore respectfully requests reconsideration of the Petition and entry of the amendment to the inventorship.

At pages 2-4 of the Office Action, claims 15-20, 24-27, 29-34, and 38-42 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,944,019 to Knudson et al. ("Knudson"), and claims 15-20, 24-29, and 38-42 were rejected under 35

U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,092,526 to LaFontaine et al. ("LaFontaine"). Applicant respectfully traverses these rejections.

Neither Knudson nor LaFontaine disclose each and every aspect of the claimed invention. For example, independent claim 15, as amended, recites a method of providing direct blood flow between a heart chamber and a coronary vessel including, among other aspects, "inserting an instrument through an anterior wall of the coronary vessel" and "radially expanding an implant within the passageway." Neither Knudson nor LaFontaine, either individually or in combination, discloses the above-quoted aspects, as recited in claim 15.

For example, Knudson does not disclose a method including "inserting an instrument through an anterior wall of the coronary vessel" and "radially expanding an implant within the passageway," as recited in independent claim 15.

Knudson discloses three approaches for inserting various embodiments of conduits into the heart wall and coronary artery. In particular, at col. 12, line 39-col. 24, line 58, Knudson discloses the use of an "open chest approach" and a "closed chest approach," wherein a superficial wall 36 of the coronary artery 30 is incised and a channel 50 is initiated into the deep coronary arterial wall 40 and through the musculature 42 of the left ventricle. (Col. 21, line 61-col. 22, line 3; and col. 23, lines 50-67.) Knudson further discloses insertion of an L- or T-shaped tube 10, 10' through the incised coronary artery and into the channel 50. While in some embodiments using the open chest or closed chest approach, Knudson may disclose that the conduit 10, 10' has varying flexibilities, Knudson does not disclose a radially expandable conduit or

radially expanding the conduit 10, 10' in conjunction with the open or closed chest approaches.

Knudson also discloses a catheter-controlled approach in Figs. 10-17 and at col. 24, line 62-col. 27, line 60. Using this approach, Knudson discloses inserting a catheter 120 in an incision in the groin 126 and advanced within the femoral artery 124, the descending aorta 128, the ascending aorta 122, and into the coronary artery 30. Neither the catheter, nor any other instrument, passes through the anterior wall of the coronary artery during the catheter-controlled approach taught by Knudson.

For at least the above reasons, therefore, Knudson fails to disclose or otherwise suggest a method including, in combination, "inserting an instrument through an anterior wall of the coronary vessel" and "radially expanding an implant within the passageway," as recited in claim 15. Thus, the Section 102(b) rejection based on Knudson should be withdrawn.

With respect to the Section 102(e) rejection based on LaFontaine, that rejection also should be withdrawn because LaFontaine does not disclose "inserting an instrument through an anterior wall of the coronary vessel" and "radially expanding an implant within the passageway," as set forth in independent claim 15. At page 4 of the Office Action, the Examiner wrote that

LaFontaine teaches that a cutting device can be used to form a lumen (i.e. channel) through heart tissue starting from the coronary artery (col. 4, lines 36-41). Since one is starting the lumen through the coronary artery, it is inherent that the device would pass first through the anterior and then through the posterior wall of the vessel and through the heart wall.

Applicant disagrees with the Examiner's conclusion. Since the cited disclosure of LaFontaine relates to percutaneous coronary artery bypass procedures, one of

ordinary skill in the art at the time of the invention would understand the disclosure at col. 4, lines 36-41, that the cutting device can be used to form a lumen through heart tissue starting from the coronary, to mean that the cutting device is not passed through the anterior wall. Instead, the cutting device 84 would be inserted percutaneously into the lumen of the coronary artery 58 (foregoing the need to place the cutting device 84 through the anterior wall), passed through posterior vessel wall 92, and then through heart tissue 86. Indeed, LaFontaine explicitly discloses that the "cutting device 84 is used to cross restriction 74 and is then manipulated to cut through vessel wall 92," wherein vessel wall 92 is the posterior wall of the coronary artery, as shown in Figs. 3, 4, 5, 5A, and 5B. Moreover, the description of crossing the restriction 74 further clarifies that the procedure is a percutaneous one whereby the cutting device travels along the lumen of the coronary artery and not through the artery's anterior wall.

In Figs. 5G-5J, LaFontaine does disclose a procedure wherein an instrument is passed through an exterior and interior walls of the coronary artery. However, in that embodiment, LaFontaine does not disclose expanding, or otherwise placing, an implant in the passageway formed in the heart wall. Instead, as shown in Fig. 5J, LaFontaine discloses ablating the myocardium to form a lumen between the left ventricle and coronary artery (see col. 7, lines 20-34).

Therefore, LaFontaine neither discloses nor otherwise suggests a method including, in combination, "inserting an instrument through an anterior wall of the coronary vessel" and "radially expanding an implant within the passageway," as recited in claim 15. Accordingly, for at least the aforementioned reasons, Applicant respectfully requests withdrawal of the Section 102(e) rejection based on LaFontaine.

At pages 5-6 of the Office Action, dependent claims 21-23 and 35-37 were rejected under 35 U.S.C. §103(a) as being unpatentable over either Knudson or LaFontaine in view of U.S. Patent No. 5,980,548 to Evans et al. ("Evans"). Applicant respectfully traverses these rejections, as Evans does not remedy the aforementioned deficiencies of Knudson and LaFontaine, and the Examiner has not asserted otherwise in the Office Action. Accordingly, for at least this reason, Applicant respectfully requests withdrawal of the Section 103(a) rejections.

At pages 6-9 of the Office Action, claims 15, 16, 20, 24-30, 33, 34, and 38-42 were rejected in an obviousness-type double patenting rejection as being unpatentable over certain claims set forth in U.S. Patent Application Nos. 10/681,323 ("the '323 application") and 10/617,176 ("the '176 application"), and U.S. Patent No. 6,638,237 ("the '237 patent"). As an initial matter, Applicant does not necessarily agree with the Examiner's characterizations concerning claims set forth in this application, as well as those set forth in the '323 application, '176 application, and '237 patent. Moreover, among other things, Applicant does not necessarily agree with the Examiner's assertions at pages 7-9 of the Office Action regarding the differences between the instant application claims and the claims of the '323 and '176 applications and the '237 patent, the conclusions of obviousness, and the conclusions of what is "well known" and "equivalent."

Nevertheless, although Applicant does not necessarily agree with the double patenting rejections or conclusions set forth in those rejections, Applicant submits herewith a Terminal Disclaimer to obviate the double patenting rejection based on the '237 patent. The filing of this Terminal Disclaimer in no way manifests an admission by

Applicant as to the propriety of the double patenting rejections. See M.P.E.P. § 804.02 citing Quad Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870, 20 USPQ2d 1392 (Fed. Cir. 1991). Applicant reserves the right to traverse the double patent rejections at a later date. Applicant respectfully requests the withdrawal of the double-patenting rejections in view of the Terminal Disclaimer filed herewith.

Regarding the double-patenting rejections based on the '323 and '176 applications, under the provisions of M.P.E.P. § 804, should the Examiner deem that this application is in condition for allowance with the exception of those double patenting rejections, Applicant requests withdrawal of the provisional double patenting rejections, since the '323 and '176 applications have not yet issued. Should double patenting rejections be maintained in the '323 and/or the '176 applications, consideration will be given to filing a Terminal Disclaimer and such Terminal Disclaimer will be filed where appropriate.

Claims 16 and 18-29 depend either directly or ultimately from claim 15 and are therefore allowable for at least the same reasons claim 15 is allowable. Moreover, at least some of claims 16 and 18-29 recite unique features and/or combinations that are neither taught nor suggested by the cited art and therefore at least some of those claims are separately patentable.

Applicant requests the withdrawal of the outstanding rejections, the entry of the inventorship amendment requested March 4, 2003, and the timely allowance of pending claims 15, 16, and 18-29.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

Please grant any extensions of time required to enter this Request for Reconsideration and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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